Supreme Court, U.S.
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No.

IN THE
Supreme Court of the United States

Lone Star Bakery, Inc., Petitioner

v.

United States of America, Respondent

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

I. Whether the Fifth Circuit Court of Appeals was incorrect in ruling that Lone Star Bakery failed, as a matter of law, to establish proximate cause when reasonable minds could draw conflicting inferences from the facts.

II. Whether the District Court erred in finding that Lone Star Bakery failed, as a matter of law, to establish a duty of care under Texas state law; the Fifth Circuit Court of Appeals found the causation issue dispositive; therefore, it did not address the issue of duty.

RULE 29.6

Petitioner, pursuant to Rule 29.6, states that it is a privately held company. There is no publicly held corporation that owns more than 10% of its stock.

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OPINIONS BELOW

The unpublished opinion of the United States District Court for the Western District of Texas, San Antonio Division, in *Lone Star Bakery, Inc. v. The United States of America* (Docket No. SA-05-CA-11-H), decided March 6, 2009, granting Respondent summary judgment, is set forth in the Appendix hereto (App.A).

The unpublished opinion of the United States Court of Appeals for the Fifth Circuit in *Lone Star Bakery, Inc. v. The United States of America* (Docket No. 09-50374), filed on November 17, 2009, affirming the District Court's granting of Respondent's summary judgment, is set forth in the Appendix hereto (App. B).

The United States Court of Appeals for the Fifth Circuit's Order denying Lone Star Bakery, Inc.'s Motion for Rehearing, filed on January 12, 2010, is set forth in the Appendix hereto (App. C).

JURISDICTION

The decision of the United States Court of Appeals for the Fifth Circuit, affirming the decision of the district court's order granting summary judgment, was handed down on November 17, 2009. A timely petition for rehearing was denied on January 12, 2010. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RELEVANT PROVISIONS INVOLVED

Federal Tort Claims Act, 28 U.S.C. § 1346(b):

"Subject to the provisions of chapter 171 of this title, the district courts, together with the United States District Court for the District of the Canal Zone and the District Court of the Virgin Islands, shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages, accruing on and after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

Chapter 1 of the FDA's Bacteriological Analytical Manual

"The adequacy and condition of the sample or specimen received for examination are of primary importance. If samples are improperly collected and mishandled or are not representative of the sampled lot, the laboratory results will be meaningless."

"There can be no compromise in the use of sterile sampling equipment and the use of aseptic technique."

"If plastic bags were used for sampling, be certain that twist wires did not puncture surrounding bags. Any cross-contamination resulting from one or more of above defects would invalidate the sample, and the collecting district should be notified."

Chapter 4 of the FDA Office of Regulatory Affairs, USFDA Investigations Manual

Subchapter 405.1
"To be useful, an Official Sample must be: handled, identified, and sealed in such a manner as to maintain its integrity as evidence, with a clear record of its chain of custody."

Subchapter 426
"Aseptic sampling is a sampling technique used to assure you are not increasing the microbial load of a product sample by your sampling method. The use of sterile sampling implements and containers and a prescribed sampling method defines aseptic sampling. This method of sampling also assures that you are not contaminating what remains in the container from which you sample."

Subchapter 426.1
"If it is necessary to open containers, draw the sample and submit it under conditions, which will

prevent multiplication or undue reduction of the bacterial population. Follow the basic principles of aseptic sampling technique. Take steps to minimize

exposure of product, sampling equipment, and the interior of sampling containers to the environment."

"Sterilized Equipment -- Use only sterilized equipment and containers."

21 CFR – 7.45 (FDA Requested Recall)

"The Commissioner of Food and Drugs or his designee under 5.20 of this chapter may request a firm to initiate a recall when the following determinations have been made:

1. That a product that has been distributed presents a risk of illness or injury or gross consumer deception.
2. That the firm has not initiated a recall of the product.
3. That an agency action is necessary to protect the public health and welfare."

STATEMENT OF THE CASE

Petitioner, Lone Star Bakery, Inc. asserts in this case that the FDA negligently collected a sample of its biscuit product, which resulted in a false positive finding. There is sufficient evidence to raise a fact issue as to whether the FDA's actions

were the proximate cause of the false positive finding. The FDA's negligence resulted in substantial monetary damages to Lone Star Bakery, Inc.

The FDA conducted an investigation at MarketFare Foods (a sandwich assembler) in Phoenix, Arizona upon learning that particular biscuit sandwiches assembled at MarketFare may be contaminated with *Listeria Monocytogenes*, a fatal bateria. Lone Star Bakery, Inc. is the manufacturer of the biscuit component of the sandwiches. The FDA collected various components of the biscuit sandwiches, i.e. biscuit, cheese, sausage, egg. The FDA reported a positive finding of *LM* in the biscuit component and the sandwich component as a whole. The FDA requested MarketFare recall the biscuit sandwiches, and MarketFare issued a recall on April 5, 2002.

The gravamen of Lone Star Bakery's claim is that the FDA employee who collected the biscuit component sample at MarketFare was negligent in the performance of his duties, and his negligence caused a false positive finding of *LM*. The FDA is mandated to follow certain procedures throughout its collection process to ensure that the integrity of the sample it collects and test is not compromised. *See Chapter 1 of the FDA's Bacteriological Analytical Manual and Chapter 4 of the FDA Office of Regulatory Affairs, USFDA Investigations Manual.*

There is sufficient evidence to draw the inference that the FDA's failure to follow its mandated rules, regulations, and directives resulted in the contamination of the biscuit component. The FDA employee that collected the biscuit component at MarketFare testified that it is possible that he may have contaminated the biscuit. The FDA employee testified that he did not place the biscuit samples in a sterile container. The FDA employee testified that when he handled the perforated pillowpak of biscuits, he did not know the pillowpak was perforated (tiny holes in the pillowpaks are necessary because the bags are heat-shrink wrapped). The FDA testified that the documents did not establish a chain of custody. Lone Star Bakery's expert testified that the FDA's failure to follow its mandated rules and regulations concerning aseptic handling and other collection processes of food sampling render any results that flow therefrom meaningless. The FDA, however, reported a positive finding of *LM*, which false positive finding caused Lone Star Bakery the damages to which it seeks herein. Lone Star Bakery has established a fact issue regarding proximate cause.

The FDA never requested that Lone Star Bakery recall any of the millions of biscuits it manufactured and distributed to customers during the same relevant time period, which is additional evidence that infers the FDA knew it caused the

positive finding of *LM* in the biscuit component it collected at MarketFare. If the FDA believed Lone Star Bakery was the source of *LM*, and knowing there were millions of biscuits distributed to Popeyes', Whataburger, and Denny's during this same time period, the FDA would be required to issue a recall, or at the very least request that Lone Star Bakery issue a voluntary recall because *LM* is a fatal bacteria. 21 CRF § 7.45. The FDA made no such request. This evidence raises an inference that the FDA was the source of the contamination from the biscuit sample it collected at MarketFare in Phoenix. To believe otherwise would be to suggest the FDA believed there were millions of biscuits distributed throughout the United States potentially contaminated with a fatal bacteria, and it chose not to request or mandate a recall. As we say in Texas, that dog don't hunt!

The United States District Court for the Western District of Texas granted the FDA's Summary Judgment finding that Lone Star Bakery had failed, as a matter of law, to establish duty and causation. The United States Fifth Circuit Court of Appeals did not address the duty issue; rather it found the causation issue to be dispositive and affirmed the District Court's Summary Judgment.

REASONS FOR GRANTING THE WRIT

As to the first question presented for review, the Fifth Circuit Court of Appeals disregarded

settled Texas law in holding that Lone Star Bakery failed as a matter of law to establish proximate cause.

The Texas Supreme Court has held that causation is a fact issue if more than one inference can be drawn from the facts. *Garza v. Alviar*, 395 S.W.2d 821, 823 (Texas 1965). It is for a jury to decide whether the FDA's admitted failure to use aseptic means caused the contamination in the biscuit sample it collected at MarketFare because reasonable minds could draw conflicting inferences from the evidence established by Lone Star Bakery. *Collora n. Navarro,*, 574 S.W.2d 65, 68 (Texas. 1978); *Peerenboom v. HSP*, 910 S.W.2d 156 (Tex. App. – Waco 1995, no writ). Further, a reasonable jury could conclude that the FDA contaminated the biscuit sample collected at MarketFare, which would explain why the FDA did not recall the millions of biscuits manufactured by Lone Star Bakery and distributed to Popeyes, Whataburger, and Dennys during this same relevant time period. *McGuire v. Overton Memorial Hosp.*, 514 S.W. 79, 85 (Tex. Civ. App. – Tyler 1974, writ ref'd n.r.e per curiam). Lone Star Bakery established more than one inference of causation; thus, the law in Texas requires that the issue must then go to the jury to weigh the credibility of the witnesses and render a finding. *Potter v. Anthony Crane Rental of Texas, Inc.*, 896 S.W.2d 845, 851 (Tex. App. – Beaumont 1995, writ denied).

The Fifth Circuit Court of Appeals erred in finding that the FDA's testimony permits an inference of breach, but it fails to raise a fact issue as to whether the FDA's conduct caused the biscuit sample to test falsely positive. Lone Star Bakery asserts the FDA caused the biscuit to test positive and the FDA asserts Lone Star Bakery was the source. Who caused the *LM* in the biscuit component is the ultimate fact issue that should be decided by a jury. The FDA handled the biscuit component that tested positive, and has admitted it did not place the sample in a sterile container. When it is established that a food sample is not collected aseptically, and there is a finding of contamination, the source of the contamination is unknown, which is why results are rendered invalid. In this case, the biscuit component was admittedly not collected aseptically, and admittedly, no chain of custody can be established by the documents. Yet, the FDA reported a finding as if it were valid and meaningful. Lone Star Bakery has established by the facts that more than a mere possibility exist that the FDA caused the contamination; the facts establish a probability, particularly when all inferences are indulged in favor of Lone Star Bakery. *Martin v. Durden*, 965 S.W.2d 562, 564 (Tex. App. – Houston [14th Dist.] 1997). The FDA did not use aseptic collection techniques or establish a documented chain of custody; thus, no one can discern with absolute certainty the source of contamination. You can, however, review the facts, weigh the credibility of the witnesses, and make

inferences as to causation and let reasonable minds decide the source of contamination. In our case, the FDA admits that its conduct may have caused the contamination in the biscuit component. In our case, the FDA admits that it did not place the biscuit component in a sterile container. In our case, the FDA admits that the documents do not establish a chain of custody. In our case, the FDA admits that it did not get a single positive finding of *LM* in any biscuit sample it collected from Lone Star Bakery's facility. In our case, the FDA admits that it did not request a recall of a single biscuit from the market. In our case, Lone Star Bakery's expert testified that the FDA failed to follow its mandated rules and regulations during the collection process at MarketFare, and those failures rendered any results that flowed therefrom meaningless and invalid. Lone Star Bakery did not just offer "pieces of evidence that pertain to the issue of proximate causation," as stated by the Fifth Circuit, Lone Star Bakery offered evidence that allows a reasonable jury to find that the FDA caused the contamination. In Texas, the question of proximate cause is a factual issue and only in extraordinary cases should this issue be taken from a jury. *Tex. Dep't of Transp. v. Olson*, 980 S.W. 890, 893 (Tex. App. – Fort Worth 1998, no pet.); *Springall v. Fredericksburg Hosp. and Clinic*, 225 S.W.2d 232, 234 (Tex. Civ. App. – San Antonio 1949, no writ). There is nothing extraordinary about this case that warrants depriving Lone Star Bakery of its right to present these established fact to the factfinder.

As to the second question presented for review, the Court below did not rule on the District Court's finding that Lone Star Bakery failed to establish a duty under Texas law. The Fifth Circuit Court of Appeals found the issue of causation dispositive, so it did not address the issue of duty.

The District Court erred in finding that the FDA did not owe a duty of care to Lone Star Bakery under Texas law.

The Fifth Circuit Court of Appeals has held that the government's failure to follow its regulations and protocols does not give rise to an action under the Federal Tort Claims Act **unless** the offending federal employee would owe a duty under state law if it were a private person or entity. *Johnson v. Sawyer,* 47 F.3d 716, 728 (5th Cir. 1995) (en banc). A private laboratory collecting and testing product for Lone Star Bakery owes a duty of care to Lone Star Bakery. The FDA collected and tested the biscuit component manufactured by Lone Star Bakery, and reported a false positive. Neither the Fifth Circuit Court of Appeals nor the Texas Supreme Court has held that no duty exists between an employer and the lab it retains. *Willis v. Roche Biomedical Laboratories, Inc.,* 61 F.3d 313, 316 (5th Cir. 1995) (case focused on relationship between employee and lab; rather than relationship between employer and laboratory); *SmithKline Beecham Corp. v. Doe,* 903 S.W.2d 347, 351 (Tex. 1995)

(case focused on whether private lab had a duty to warn testee that poppy seeds could effect test results).

In our case, the FDA's failure to follow its rules, regulations, and guidelines does give rise to an action under the FTCA because if the FDA were a private entity, it would, under state law, owe a duty of care to Lone Star Bakery. This position is not inconsistent with the Fifth Circuit Court of Appeals decisions. *See Quijano v. United States,* 325 F.3d 564, 568 (5th Cir. 2003); *Johnson v. Sawyer,* 47 F.3d 716, 728 (5th Cir. 1995) (federal regulations may be evidence of negligence if duty exist under state law.) The FDA does have a duty to exercise reasonable care in performing its operational tasks, and in this case, fact issues exist as to whether those tasks were performed while exercising due care.

The Texas Supreme Court has held that in determining whether a legal duty exist, you must consider several interrelated factors, such as the risk, foreseeability, likelihood of injury weighed against the social utility of the actor's conduct, the magnitude of the burden of guarding against the injury, and the consequences of placing the burden on the defendant. *Greater Houston Transp. Co. v. Phillips,* 801 S.W.2d 53, 525. Considering all these factors, the FDA owed a duty of care to Lone Star Bakery.

CONCLUSION

Petitioner respectfully requests the issuance of a writ of certiorari to the United States Court of Appeals for the Fifth Circuit, and ultimately, to vacate that judgment and remand the matter for trial, and provide petitioner with such other fair and just relief to which it is entitled in this case.

Respectfully submitted,

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